

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The Effect of Leisure-time Physical Activity Program on Activity Daily Living and Hope in the Elderly men

Protocol summary

Study aim

The Effect of Leisure Time Physical Activity Program on Activity Daily Living and Hope in Elderly Men

Design

A clinical trial with control and intervention groups, with parallel groups, double-blind, randomized on 60 elderly samples. Statistical software was used for randomization.

Settings and conduct

Selected park or parks with ease of access for samples

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 60 to 80 years old; absence of acute underlying disease; absence of debilitating motor problems and defects. Exclusion criteria: acute illness and hospitalization during the study; inability to tolerate research interventions.

Intervention groups

Before starting the intervention, Barthel and Adult Hope Scale (AHS) demographic information questionnaires are completed by the researcher through a face-to-face interview with the elderly. Leisure time physical activities are performed in 8 sessions, once a week (8 weeks) and each session lasts at least 45 minutes in groups and in three groups of ten people. So that all three groups receive interventions on three different days every week. The intervention items include walking for thirty minutes, balance exercise for the elderly for fifteen minutes (including exercises: standing on one leg - standing on the toe - walking on the heel and toes - moving by sticking the heel to the big toe - walking in the figure of eight in English. Each for three minutes). The control group will receive the usual physical activities performed by themselves and the contingency plans of the respective health center. Two weeks after the end of the intervention, the mentioned questionnaires will be completed again.

Main outcome variables

Activity Daily Living; hope

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230224057518N1**

Registration date: **2023-07-10, 1402/04/19**

Registration timing: **retrospective**

Last update: **2023-07-10, 1402/04/19**

Update count: **0**

Registration date

2023-07-10, 1402/04/19

Registrant information

Name

Mahdi Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3662 8015

Email address

azizim982@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

2023-04-21, 1402/02/01

Actual recruitment end date

2023-05-05, 1402/02/15

Trial completion date

empty

Scientific title

The Effect of Leisure-time Physical Activity Program on Activity Daily Living and Hope in the Elderly men

Public title

The Effect of Leisure-time Physical Activity Program on Activity Daily Living and Hope in the Elderly men

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 60 to 80 years Living at home Absence of acute underlying disease Ability to communicate verbally Not participating in similar programs No use of drugs and alcohol The absence of a stressful event within the last 6 months Informed consent Absence of disabling motor problems and defects Absence of sensory disorders (such as vision and hearing disorders)

Exclusion criteria:

Acute illness and hospitalization during the study Absence of more than one session Inability to tolerate research interventions

Age

From **60 years** old to **80 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of samples into two intervention and control groups using SPSS statistical software and concealment of random allocation using two sealed envelopes, which specify the control and intervention groups, and the researcher is not aware of its content before random allocation. .

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences, Mashhad College of Nursing and Midwifery

Street address

Faculty of Nursing and Midwifery, Doctora Crossroad, Ibn Sina St., Mashhad, Khorasan Razavi

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Mashhad

Province

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Postal code

9137913199

Approval date

2023-02-27, 1401/12/08

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.103

Health conditions studied

1

Description of health condition studied

Elderly

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The degree of dependency in Activity Daily Living

Timepoint

Before the start of the intervention and two weeks after the end of the intervention

Method of measurement

Barthel Activity Daily Living Scale

2

Description

Degree of hope

Timepoint

Before the start of the intervention and two weeks after the end of the intervention

Method of measurement

Snyder Hope Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention items include walking for thirty minutes, balance training for the elderly for fifteen minutes (including exercises: standing on one leg - standing on the toe - walking on the heel and toes - moving by attaching the heel to the big toe- walking in the form of eight in English. each for three minutes). In order to facilitate the intervention, the intervention group is divided into three groups of ten people, and the

mentioned interventions are performed equally for all three groups, and there is no special difference between the members of the intervention groups, nor in the interventions performed.

Category

Lifestyle

2

Description

Control group: They will receive the usual physical activities performed by themselves and the possible plans of the relevant health center. No other specific intervention in the study will be done for them.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Safari comprehensive Health Center

Full name of responsible person

Mahdi Azizi

Street address

8th Taban Avenue, 23d Hashemyie Boulevard,
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2

Recruitment center

Name of recruitment center

Abobargh Health Center

Full name of responsible person

Mahdi Azizi

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Villa Ave, Facouri Boulevard, Mashhad City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour Mobarhan

Street address

Gharashi Building, Next to Hoveyze Cinema,
Daneshgah Ave, Mashhad City

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vcresraech@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahdi Azizi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Part of the individual data of the participants, such as information about the main outcome or the same information

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Academic and scientific researchers

Under which criteria data/document could be used

A practical program for applying the results in society

From where data/document is obtainable

Correspondence by email to: AziziM982@mums.ac.ir

What processes are involved for a request to access data/document

Providing the reason for the request and data usage and, if approved, providing documentation

Comments